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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------|-----------------------------------------|----------------------|----------------------------|------------------|
| 10/529,649 | 10/11/2005 | Giovanni Pozzi | 2965-195 | 1389 |
| 1425 K STREET, 14.W. | | | INER | |
| | | | BERCH, MARK L | |
| SUITE 800 WASHINGTO | N. DC 20005 | | ART UNIT PAPER NUMBER 1624 | |
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| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 10/16/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

| <u> </u> | Application No. | Applicant(s) | | |
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| | 10/529,649 | POZZI ET AL. | | |
| Office Action Summary | Examiner | Art Unit | | |
| | /Mark L. Berch/ | 1624 | | |
| The MAILING DATE of this communication Period for Reply | n appears on the cover sheet w | vith the correspondence add | dress | |
| A SHORTENED STATUTORY PERIOD FOR RI WHICHEVER IS LONGER, FROM THE MAILIN - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communicatio - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by s - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THIS COMMUN FR 1.136(a). In no event, however, may a n eriod will apply and will expire SIX (6) MO statute, cause the application to become A | ICATION. reply be timely filed NTHS from the mailing date of this co. BANDONED (35 U.S.C. § 133). | | |
| Status | | | | |
| Responsive to communication(s) filed on (2a) ☐ This action is FINAL . 2b) ☐ Since this application is in condition for all closed in accordance with the practice uncondition. | This action is non-final. owance except for formal materials | • | merits is | |
| Disposition of Claims | | • | | |
| 4) ⊠ Claim(s) 1-16 and 18 is/are pending in the 4a) Of the above claim(s) is/are with 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-16 and 18 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction a | ndrawn from consideration. | , | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Example 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the control of the sheet of | accepted or b) objected to the drawing(s) be held in abeya prrection is required if the drawing | nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CF | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview | Summary (PTO-413) | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948 Information Disclosure Statement(s) (PTO-1449 or PTO/SI Paper No(s)/Mail Date | | (s)/Mail Date Informal Patent Application (PTO | -152) | |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/04/2007 has been entered.

The anticipation rejection over 6093814 is overcome by the "isolated" requirement. Likewise, the "crystal" of claim 18 avoid anticipation. There is no motivation present to isolate or to convert into crystal form the tributyl ammonium salt of tritylated cefdinir so no rejection under 35 USC 103(a) is made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear what is entailed by "isolated": Isolated from what? Is it isolated from something, e.g. just from a reaction medium, or is it isolated from everything, i.e. pure. The specification gives no guidance, as the compound is not described as isolated.

Claims 1-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Z choices 2, 3, 10-14, does not reasonably provide enablement the others. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The adducts of the strong acids are not enabled. Thus, for the first choice, the adduct is of HCl, i.e. an HCl salt. As soon as the amine is added, it will neutralize the HCl present. Only after all this HCl is neutralized can the actual salt be formed. Thus, the adduct does not form.

Claim Objections

Claims 1, 13 and 15, third from last line, each have a raised number 2 which should be subscript.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 · 3:45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private

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PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark L. Berch/

Primary Examiner

Art Unit 1624

10/3/07